

PTO/SB/21 (08-03)

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<b>TRANSMITTAL FORM</b> <i>(to be used for all correspondence after initial filing)</i>	Application Number	10/777,838
	Filing Date	February 12, 2004
	First Named Inventor	Mark K. Wedel
	Art Unit	To Be Determined
	Examiner Name	To Be Determined
Total Number of Pages in This Submission	Attorney Docket Number	ISIC0008-100 (FMDL0001US)

ENCLOSURES (check all that apply)				
<input type="checkbox"/> Fee Transmittal Form  <input type="checkbox"/> Fee Attached  <input type="checkbox"/> Amendment / Reply  <input type="checkbox"/> After Final  <input type="checkbox"/> Affidavits/declaration(s)  <input type="checkbox"/> Extension of Time Request  <input type="checkbox"/> Express Abandonment Request  <input checked="" type="checkbox"/> Information Disclosure Statement  <input type="checkbox"/> Certified Copy of Priority Document(s)  <input type="checkbox"/> Response to Missing Parts/ Incomplete Application  <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s)  <input type="checkbox"/> Licensing-related Papers  <input type="checkbox"/> Petition  <input type="checkbox"/> Petition to Convert to a Provisional Application  <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address  <input type="checkbox"/> Terminal Disclaimer  <input type="checkbox"/> Request for Refund  <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group  <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences  <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)  <input type="checkbox"/> Proprietary Information  <input type="checkbox"/> Status Letter  <input checked="" type="checkbox"/> Other Enclosure(s) <i>(please identify below):</i>  <b>Form PTO SB/08a and Form PTO SB/08b (8 pp.); (91) References Cited; (69) References enclosed.</b>		
<table border="1"><tr><td>Remarks</td><td></td></tr></table>			Remarks	
Remarks				

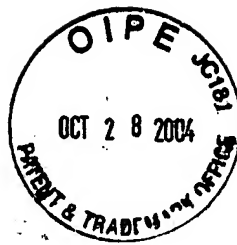
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Firm or Individual name	Quan Le Nguyen, Registration No. 46,957
Signature	
Date	10/26/04

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Signature		Date	10/26/04

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ISIC0008-100 (FMDL0001US)



PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In Re Application of: **Wedel and Miner Jr.**

Serial No.: **10/777,838**

Group Art Unit: **To Be Determined**


Filing Date: **February 12, 2004**

Examiner: **To Be Determined**

For: **Compositions And Methods For Treatment Of Pouchitis**

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On 10/26/04

  
Quan Le Nguyen, Registration No. 46,957

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§ 1.56 and in accordance with 37 C.F.R. §§ 1.97 and 1.98, information relating to the above-identified application is hereby disclosed, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO Forms SB/08a and SB/08b, formerly known as PTO Form 1449 submitted herewith.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

**This Information Disclosure Statement is being filed:**

- ☐ within three months of the filing date of the patent application.
- ☐ within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application.
- ☒ **before** the mailing date of a first Office Action on the merits.
- ☐ **after** the mailing date of a first Office Action on the merits, but before the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, and accordingly is accompanied by:
  - ☐ the Statement under 37 C.F.R. § 1.97(e) (see “Statement” below);
- or**
- ☐ the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p); or
- ☐ No fee is owed by the applicant(s).
- ☐ In accordance with 37 C.F.R. § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e) (see “Statement” below) and the fee of \$180.00 as set forth in 37 C.F.R. § 1.17(p), is attached.
- ☐ **after** the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, but before the payment of the Issue Fee, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e), (see “Statement,” and “Fees” below).
- ☒ Copies of References (except U.S. Patents Documents) cited on the attached PTO Forms SB/08a and SB/08b, formerly known as PTO Form 1449 are enclosed.

**EXCEPT THAT:**

- ☐ In view of the voluminous nature of reference @@, and the likelihood that this reference is available to the Examiner, copies are not enclosed herewith.
- ☐ In accordance with 37 C.F.R. § 1.98(d), copies of the following references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

**Statement under 37 C.F.R. § 1.97(e)**

- ☐ The undersigned attorney hereby states that each item information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.

**Fees**

- ☒ No Fee is owed by the applicant(s).
- ☐ The Information Disclosure Statement Fee of \$180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.

**Method of Payment of Fees**

- ☐ Attached is a check in the amount of \$\_\_\_\_\_. This form is submitted in duplicate.
- ☐ Charge Deposit Account No. 50-1275 in the amount of \$180.00. This form is submitted in duplicate.
- ☒ Please charge any deficiency or credit any overpayment to Deposit Account 50-1275.
- ☐ No fee or Statement is required under 37 C.F.R. § 1.97(b).

Respectfully submitted,

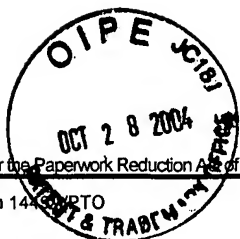


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Quan Le Nguyen.  
Registration No. 46,957

Dated: 10/26/04

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 8

**Complete if Known**

Application Number	10777,838
Filing Date	February 12, 2004
First Named Inventor	Mark K. Wedel
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	ISIC0008-100 (FMDL0001US)

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	A1	US-5,595,978	01/21/1997	Draper et al	
	A2	US- 5,705,188	01/06/1998	Junichi et al	
	A3	US- 5,135,917	08/04/1992	Burch	
	A4	US- 5,098,890	03/24/1992	Gewirtz et al.	
	A5	US- 5,087,617	02/11/1992	Smith	
	A6	US- 5,166,195	11/24/1992	Ecker	
	A7	US- 5,194,428	03/16/1993	Agrawal et al.	
	A8	US- 5,286,717	02/15/1994	Cohen et al.	
	A9	US- 5,276,019	01/04/1994	Cohen et al.	
	A10	US- 5,264,423	11/23/1993	Cohen et al.	
	A11	US- 4,689,320	08/25/1987	Kaji	
	A12	US- 5,242,906	09/07/1993	Pagano et al.	
	A13	US- 5,514,788	05/07/1996	Bennett et al.	
	A14	US- 5,591,623	01/07/1997	Bennett et al.	
	A15	US- 3,687,808			
	A16	US- 5,543,508	08/06/1996	Haseloff et al	
	A17	US- 5,545,729	08/13/1996	Goodchild et al	
	A18	US- 5,716,780	02/10/1998	Edwards et al	
	A19	US- 5,672,359	09/30/1997	Digenis et al	
	A20	US- 5,674,530	10/07/1997	Amidon et al	

**FOREIGN PATENT DOCUMENTS**

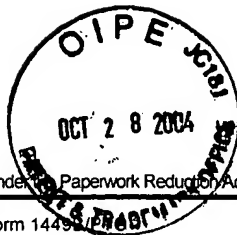
Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	A21	WO97/30731	08/28/1997	The Immune Response Corp.		
	A22	WO93/24510	12/09/1993	Gosselin et al		

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 2 of 8

**Complete if Known**

Application Number	101777,838
Filing Date	February 12, 2004
First Named Inventor	Mark K. Wedel
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	ISIC0008-100 (FMDL0001US)

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	B1	ROBERTSON, "Crohn's Trial Shows The Pros Of Antisense," <i>Nature Biotechnol.</i> (1997) 15:209.	
	B2	<i>Genetic Engineering News</i> , "ISIS Pharmaceuticals Demonstrates Efficacy In Chron's Disease With Its Antisense Drug," (1997) 17:1, 34.	
	B3	SVANINGER, et al., "Incidence And Characteristics Of Pouchitis In The Kock Continent Heostomy And The Pelvic Pouch," <i>Scand. J. Gastroenterol.</i> (1993) 28:695-700.	
	B4	PENNA, et al., "Pouchitis After Ileal Pouch-Anal Anastomosis For Ulcerative Colitis Occurs With Increased Frequency In Patients With Associated Primary Sclerosing Cholangitis," <i>Gut</i> (1996) 38:234-239.	
	B5	SANDBORN, "Pouchitis: Definition, Risk Factors, Frequency, Natural History, Classification, And Public Health Perspective," in <i>Trends in Inflammatory Bowel Disease</i> , 1996, pp. 51-63.	
	B6	TREMAINE, et al., "Bismuth Carbomer Foam Enemas For Active Chronic Pouchitis: A Randomized, Double-Blind, Placebo-Controlled Trial," <i>Aliment. Pharmacol. Ther.</i> , (1997) 11:1041-1046.	
	B7	VAN BERGE-HENEGOUWEN, et al., "Pharmacology Of Chenodeoxycholic Acid," <i>Gastroenterology</i> (1977) 73:300-309.	
	B8	MIYAO, et al., "Stability And Pharmacokinetic Characteristics Of Oligonucleotides Modified At Terminal Linkages In Mice," <i>Antisense Res. Dev.</i> (1995) 5:115-121.	
	B9	TAKAKURA, et al., "Uptake Characteristics Of Oligonucleotides In The Isolated Rat Liver Perfusion System," <i>Antisense Nucleic Acid Drug Dev.</i> (1996) 6:177-183.	
	B10	MURANISHI, "Absorption Enhancers," <i>Crit. Rev. Ther. Drug Carrier Sys.</i> (1990) 7:1-33.	
	B11	LEE, "Mucosal Penetration Enhancers For Facilitation Of Peptide And Protein Drug Absorption," <i>Crit. Rev. Ther. Drug Carrier Sys.</i> (1991) 8:91-92.	

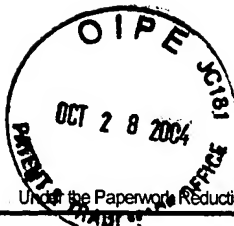
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 3 of 8

**Complete if Known**

Application Number	10/777,838
Filing Date	February 12, 2004
First Named Inventor	Mark K. Wedel
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	ISIC0008-100 (FMDL0001US)

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	B12	BENET, et al., "Pharmacokinetics, The Dynamics Of Drug Absorption, Distribution, And Elimination," <i>The Pharmacological Basis of Therapeutics</i> , 9 <sup>th</sup> ed., 1996, pp. 3-9.	
	B13	HIRAHATA, et al., <i>Gan To Kagaku Ryoho</i> (1992) 19 (10 Supp):1591-1594 (No English Translation).	
	B14	SOMOGYI, et al., "Evaluation Of The Intestinal Absorption Of Erythromycin In Man: Absolute Bioavailability And Comparison With Enteric coated Erythromycin," <i>Pharm. Res.</i> (1995) 12:149-154.	
	B15	AKAMO, et al., "Chemotherapy Targeting Regional Lymph Nodes By Gastric Submucosal Injection Of Liposomal Adriamycin In Patients With Gastric Carcinoma," <i>Japan. J. Cancer Res.</i> ( 1994) 85:652-658.	
	B16	INOUE, et al., "Trial Of Electrolyzed Strong Acid Aqueous Solution Lavage In The Treatment Of Peritonitis And Intraperitoneal Abscess," <i>Artif. Organs</i> (1997) 21:28-31.	
	B17	PENNINGTON, et al., "Review Article: Artificial Nutritional Support For Improved Patient Care," <i>Aliment. Pharmacol. Ther.</i> (1995) 9:471-481.	
	B18	HARVEY, "Absorption Of Drugs," <i>Remington's Pharmaceutical Sciences</i> , 18 <sup>th</sup> ed., Chap. 35, Gennaro, ed., Mack Pub. Co., 1990, p. 711.	
	B19	TAKAHASHI, et al., "The Use Of A Perfluorochemical Emulsion As A Vascular Perfusate In Drug Absorption," <i>J. Pharm. Pharmacol.</i> (1988) 40:252-257.	
	B20	EL-HARIRI, et al., "The Mitigating Effects Of Phosphatidylcholines On Bile Salt-And Lysophosphatidylcholine-Induced Membrane Damage," <i>J. Pharm. Pharmacol.</i> (1992) 44:651-654.	
	B21	YAMAMOTO, et al., "A Mechanistic Study On Enhancement Of Rectal Permeability To Insulin In The Albino Rabbit," <i>J. Pharm. Exp. Ther.</i> (1992) 263:25-31.	
	B22	YAMASHITA, et al., "Effect Of Adjuvants On Charge-Selective Permeability And Electrical Resistance Of Rat Jejunal Membrane," <i>J. Pharm. Sci.</i> (1990) 79:579-583.	

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SignatureDate  
Considered

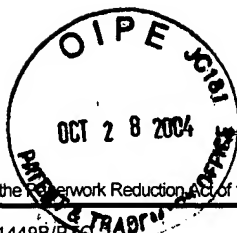
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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STATEMENT BY APPLICANT**

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Sheet 4 of 8

**Complete if Known**

Application Number	10/777,838
Filing Date	February 12, 2004
First Named Inventor	Mark K. Wedel
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	ISIC0008-100 (FMDL0001US)

**NON PATENT LITERATURE DOCUMENTS**

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	B23	BUUR, et al., "Penetration Of 5-Fluorouracil And Prodrugs Across The Intestine Of The Albino Rabbit: Evidence For Shift In Absorption Site From The Upper To The Lower Region Of The Gastrointestinal Tract By Prodrugs," <i>J. Control. Rel.</i> (1990) 14:43-51.	
	B24	YAMASHITA, et al., "Effects Of Diclofenac Sodium And Disodium Ethylenediaminetetraacetate On Electrical Parameters Of The Mucosal Membrane And Their Relation To The Permeability Enhancing Effects In The Rat Jejunum," <i>J. Pharm. Pharmacol.</i> (1987) 39:621-626.	
	B25	DUSTIN and SPRINGER, "Lymphocyte Function-Associated Antigen-1 (LFA-1) Interaction With Intercellular Adhesion Molecule-1 (ICAM-1) Is One Of At Least Three Mechanisms For Lymphocyte Adhesion To Cultured Endothelial Cells," <i>J. Cell. Biol.</i> (1988) 107:321-331.	
	B26	ALBERT, et al., "Antisense Knockouts: Molecular Scalpels For The Dissection Of Signal Transduction," <i>TIPS</i> (1994) 15:250-254.	
	B27	KROSCWITZ, "Polynucleotides," <i>Concise Encyclopedia of Polymer Science and Engineering</i> , Wiley & Sons, 1990, pp. 858-859	
	B28	ENGLISH, et al., "Chemically Modified Oligonucleotides As Probes And Inhibitors," <i>Angewandte Chemie</i> , Intl. Ed. (1991) 30:613-629.	
	B29	SANGVHI, "Heterocyclic Base Modifications In Nucleic Acides And Their Applications In Antisense Oligonucleotides," <i>Antisense Research and Applications</i> , Chap. 15, 1993, pp. 273-288.	
	B30	MARTIN, et al., <i>Helv. Chim. Acta.</i> (1995) 78:486-504 (No English Translation).	
	B31	LETSINGER, et al., "Cholesteryl-Conjugated Oligonucleotides: Synthesis, Properties, And Activity As Inhibitors Of Replication Of Human Immunodeficiency Virus In Cell Culture," <i>Proc. Natl. Acad. Sci.</i> , (1989) 86:6553-6556.	
	B32	MANOHARAN, et al., "Cholic Acid-Oligonucleotide Conjugates For Antisense Applications," <i>Bioorg. Med. Chem. Lett.</i> (1994) 4:1053-1060.	
	B33	MANOHARAN, et al., "Chemical Modifications To Improve Uptake And Bioavailability Of Antisense Oligonucleotides," <i>Ann. NY Acad. Sci.</i> (1992) 660:306-309.	

Examiner  
SignatureDate  
Considered

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 5 of 8

**Complete if Known**

Application Number	10/777,838
Filing Date	February 12, 2004
First Named Inventor	Mark K. Wedel
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	ISIC0008-100 (FMDL0001US)

**NON PATENT LITERATURE DOCUMENTS**

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	B35	OBERHAUSER, et al., "Effective Incorporation Of 2'-O-Methyl-Oligoribonucleotides Into Liposomes and Enhanced Cell Association Through Modification With Thiocholesterol," <i>Nucleic Acids. Res.</i> (1992) 20:533-538.	
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	B40	SHEA, et al., "Synthesis, Hybridization Properties And Antiviral Activity Of Lipid-Oligodeoxynucleotide Conjugates," <i>Nucleic Acids Res.</i> (1990) 18:3777-3783.	
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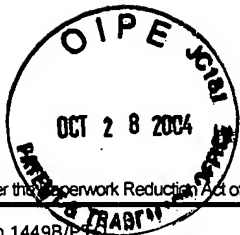
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Sheet 6 of 8

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Application Number	10/777,838
Filing Date	February 12, 2004
First Named Inventor	Mark K. Wedel
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	ISIC0008-100 (FMDL0001US)

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	B45	BUZAYAN, et al., "Satellite Tobacco Ringspot Virus RNA: A Subset Of The RNA Sequence Is Sufficient For Autolytic Processing," <i>Proc. Natl. Acad. Sci. USA</i> (1986) 83:8859-8862.	
	B46	FORSTER, et al., "Self-Cleavage Of Virusoid RNA Is Performed By The Proposed 55-Nucleotide Active Site," <i>Cell</i> (1987) 50:9-16.	
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	B48	GUERRIER-TAKADA, et al., "Phenotypic Conversion Of Drug-Resistant Bacteria To Drug Sensitivity," <i>Proc. Natl. Acad. Sci.</i> (1997) 94:8468-8472.	
	B49	HASELOFF, et al., Simple RNA Enzymes With New And Highly Specific Endoribonuclease Activities," <i>Nature</i> (1988) 334:585-591.	
	B50	BAKER, et al., "Cleavage Of The 5' Cap Structure Of mRNA By A Europium(III) Macrocyclic Complex With Pendant Alcohol Groups," <i>J. Am. Chem. Soc.</i> (1997) 119:8749-8755.	
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	B54	SMITH, "Automated Synthesis And Sequence Analysis Of Biological Macromolecules," <i>Anal. Chem.</i> (1988) 60:381A-390A.	
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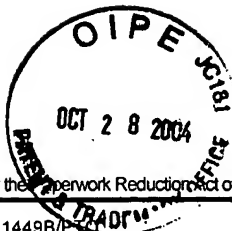
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Sheet 7 of 8

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Filing Date	February 12, 2004
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Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
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	B56	CROOKE, "Progress In Antisense Therapeutics," <i>Hematologic Pathol.</i> (1995) 9:59-72.	
	B57	IDSON, "Pharmaceutical Emulsions," <i>Pharmacological Dosage Forms</i> , 1988, p. 199-243.	
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	B60	RIEGER, "Surfactants," <i>Pharmaceutical Dosage Forms</i> , 1988, pp. 285-366.	
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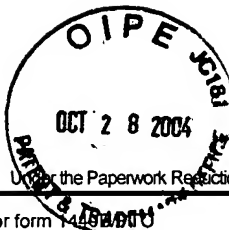
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	B67	DEAN, et al., "Inhibition Of Protein Kinase C- $\alpha$ Expression In Mice After Systemic Administration Of Phosphorothioate Antisense Oligodeoxynucleotides," <i>Proc. Natl. Acad. Sci.</i> (1994) 91:11762-11766.	
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